IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Jaime L. Rugnetta et al.	)	Examiner: Nicole R. Kramer
	)	
Serial No.: 10/670,985	)	Group Art Unit: 3762
	)	
Filed: September 25, 2003	)	Attorney Docket: 279.607US1
	)	
For: LEAD SYSTEM HAVING LEAD BODY WITH MINIMIZED CROSS-SECTION		

REPLY BRIEF UNDER 37 C.F.R § 41.41

Mail Stop Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam:

This Reply Brief is filed in response to the Examiner's Answer (hereinafter "Answer"), mailed on May 9, 2007, and supplements the Appeal Brief filed by the Appellant on January 15, 2007. If necessary, please charge any additional fees or credit overpayments to Deposit Account No. 19-0743.

REPLY

The Appellant has reviewed the Answer, and believes the statements in the original Appeal Brief remain accurate and compelling. In responding to the Answer, the Appellant wishes to further (1) clarify certain points of distinction between the pending claims and the cited references and (2) comment on the inability to meet the burden of proof for a showing of obviousness in response to the newly presented comments.

Reply to Examiner's Answer (10) Response to Argument:

Comment #1:

The Answer at page 13 contends:

> Although not explicitly stated in Huenpenbecker [sic], passive tines such as the ones illustrated in Huenpenbecker [sic] are necessarily are [sic] formed of a flexible material such that the tines fold/collapse against the lead body during insertion into the patient. In the Final Rejection, Examiner cited numerous patents to support this assertion . . . .

Although the Answer purports to cite references related to "passive tines . . . that . . . fold/collapse against the lead body during insertion into the patient", Appellant cannot find in Huepenbecker et al. or any of the cited references discussion related to the tines being recessed away from a first recessed portion.

The Answer at page 14, among other places, further contends:

> When the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine because the bottom surface of tines would contact the outer surface of sleeve 36 (which forms the second recessed portion), thus leaving the first portion (which is illustrated as smaller in cross-section than the second recessed portion) recessed away from the bottom surface of the tine.

Appellant submits that neither Huepenbecker et al. nor the cited references enable such statements regarding the first recessed portion "necessarily" being recessed away from the

bottom surface of the tine. Appellant cannot find support for this contention of the Answer in Huepenbecker et al. or the cited references. Therefore, Appellant respectfully submits that the Examiner is relying on either Official Notice, or the personal knowledge of the Examiner. Appellant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertion. Appellant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertion, or in the alternative, withdrawal of this assertion from the rejection.

In brief, Appellant submits that the Answer has failed to meet the burden of proof for a showing of anticipation by Huepenbecker et al. of, for example, claims 1, 14, and 15.

Comment #2:

The Answer at page 14 contends:

> The axial view of Figure 4 [of Huepenbecker et al.] shows the diameter of the first recessed portion to be smaller than the diameter of the second recessed portion. Since cross-sectional area is a direct function of diameter size, Examiner maintains that the cross-sectional area of the first recessed portion must necessarily be smaller than the cross-sectional area of the second recessed portion.

Contrary to the position taken by the Answer, Appellant again submits that neither Figure 4 nor any other part of Huepenbecker et al. supports such statements. Appellant reiterates the assertion that one skilled in the art could not determine the cross-sectional areas of what the Answer identifies as the first and second recessed portions of Huepenbecker et al. given only a cross section along a single axial plane, nor would one skilled in the art be able to identify the widths of what the Answer identifies as the first and second recessed portions of Huepenbecker et al. as being diameters. Given the single axial cross section of Figure 4 of Huepenbecker et al., without more, Appellant submits that the above-cited statements of the Answer are baseless.

In brief, Appellant submits that the Answer has failed to meet the burden of proof for a showing of anticipation by Huepenbecker et al. of, for example, claims 3, 9, 19, and 20.

Comment #3:

With respect to claims 7 and 8, the Answer at page 15 contends:

> Since the axial view of Figure 4 [of Huepenbecker et al.] shows the diameter of the first recessed portion to be smaller than the diameter of the second recessed portion, Examiner considers the cross-sectional area of the first recessed portion to be different from the second cross-sectional shape. In essence, Examiner considers the broadest reasonable interpretation of the "different shape" to encompass identical figures of different sizes.

Appellant cannot find support in the specification of Huepenbecker et al. for these assertions. Appellant can find no recitations related to the cross-sectional areas of any portions of the Huepenbecker et al. device. Further, it is unclear how these conclusions can be reached when Figure 4 only illustrates an axial cross-section. Appellant submits that one skilled in the art could not determine the cross-sectional areas or shapes of what the Answer identifies as the first and second recessed portions of Huepenbecker et al. given only a cross section along a single longitudinal plane, nor would one skilled in the art be able to identify the widths of what the Answer identifies as the first and second recessed portions of Huepenbecker et al. as being diameters. Given the single longitudinal cross section of Figure 4 of Huepenbecker et al., without more, Appellant submits that the above-cited statements of the Answer are baseless.

In brief, Appellant submits that the Answer has failed to meet the burden of proof for a showing of anticipation by Huepenbecker et al. of claims 7 and 8.

Comment #4:

The Answer at page 18 contends:

> Although not explicitly stated in Laske, tines such as the ones illustrated in Laske are necessarily are [sic] formed of a flexible material such that the tines fold/collapse against the lead body during insertion into the patient. In the Final Rejection, Examiner cited numerous patents to support this assertion . . . .

Although the Answer purports to cite references related to "tines . . . that . . . fold/collapse against the lead body during insertion into the patient", Appellant cannot find in Laske et al. or any of the cited references discussion related to the tines being recessed away from a first recessed portion.

The Answer at page 19, among other places, further contends:

> When the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine because the bottom surface of tines would contact the outer surface lead body (which forms the second recessed portion), thus leaving the first portion or groove 152 (which is illustrated as smaller in cross-section than the second recessed portion) recessed away from the bottom surface of the tine.

Appellant submits that neither Laske et al. nor the cited references enable such statements regarding the first recessed portion "necessarily" being recessed away from the bottom surface of the tine. Appellant cannot find support for this contention of the Answer in Laske et al. or the cited references. Therefore, Appellant respectfully submits that the Examiner is relying on either Official Notice, or the personal knowledge of the Examiner. Appellant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertion. Appellant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertion, or in the alternative, withdrawal of this assertion from the rejection.

In brief, Appellant submits that the Answer has failed to meet the burden of proof for a showing of anticipation by Laske et al. of, for example, claims 1, 14, and 15.

Comment #5:

The Answer at page 20 contends:

> The axial view of Figure 5 [of Laske et al.] shows the diameter of the first recessed portion to be smaller than the diameter of the second recessed portion. Since cross-sectional area is a direct function of diameter size, Examiner maintains that the cross-sectional area of the first recessed portion must necessarily be

> smaller than the cross-sectional area of the second recessed portion.

Contrary to the position taken by the Answer, Appellant again submits that neither Figure 5 nor any other part of Laske et al. supports such statements. Appellant reiterates the assertion that one skilled in the art could not determine the cross-sectional areas of what the Answer identifies as the first and second recessed portions of Laske et al. given only a cross section along a single axial plane, nor would one skilled in the art be able to identify the widths of what the Answer identifies as the first and second recessed portions of Laske et al. as being diameters. Given the single axial cross section of Figure 5 of Laske et al., without more, Appellant submits that the above-cited statements of the Answer are baseless.

In brief, Appellant submits that the Answer has failed to meet the burden of proof for a showing of anticipation by Laske et al. of, for example, claims 3, 9, 19, and 20.

Comment #6:

With respect to claims 7 and 8, the Answer at pages 20-21 contends:

> Since the axial view of Figure 5 [of Laske et al.] shows the diameter of the first recessed portion to be smaller than the diameter of the second recessed portion, Examiner considers the cross-sectional area of the first recessed portion to be different from the second cross-sectional shape. In essence, Examiner considers the broadest reasonable interpretation of the "different shape" to encompass identical figures of different sizes.

Appellant cannot find support in the specification of Laske et al. for these assertions. Appellant can find no recitations related to the cross-sectional areas of any portions of the Laske et al. device. Further, it is unclear how these conclusions can be reached when Figure 5 only illustrates an axial cross-section. Appellant submits that one skilled in the art could not determine the cross-sectional areas or shapes of what the Answer identifies as the first and second recessed portions of Laske et al. given only a cross section along a single longitudinal plane, nor would one skilled in the art be able to identify the widths of what the Answer

identifies as the first and second recessed portions of Laske et al. as being diameters. Given the single longitudinal cross section of Figure 5 of Laske et al., without more, Appellant submits that the above-cited statements of the Answer are baseless.

In brief, Appellant submits that the Answer has failed to meet the burden of proof for a showing of anticipation by Laske et al. of claims 7 and 8.

Comment #7:

With respect to claims 2, 5, 11, 13, 17, and 18, the Answer at page 21 contends:

> The motivation to combine the references (to ensure that the lead body is sufficiently strong during implantation) is based on common sense and in the knowledge generally available to one of ordinary skill in the art. . . . [A]dded material in the area of the recesses 167, as shown in Figure 10 of Alferness et al., would necessarily strengthen the lead body at the distal end thereof such that it is sufficiently strong to be tracked through a patient's vasculature system to the implantation site of the endocardium.

Appellant respectfully submits that these statements are unsupported by the cited references. Appellant respectfully submits that neither Huepenbecker et al. (or Laske et al.) nor Alferness et al. enables such statements, and therefore the Answer is relying on either Official Notice, or the personal knowledge of the Examiner. Appellant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertions. Appellant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertions, or in the alternative, withdrawal of these assertions from the rejection. Furthermore, it is unclear why Huepenbecker et al. would be in need of such a selective modification.

In brief, Appellant submits that the Answer has failed to meet the burden of proof for a showing of obviousness by the proposed combination.

Comment #8:

With respect to claims 2, 5, 11, 13, 17, and 18, the Answer at pages 21-2 contends:

> [M]odifying the external groove 152 of Laske et al. such that it only extends around a portion of the perimeter of the lead body in order to ensure that sheath 122 is sufficiently strong during implantation is consistent with the teachings of Laske. So long as the sheath 122 may be readily separated when force is applied thereto, it would be desirable to modify the distal end of the lead as described in the rejection above to ensure that sheath 122 is sufficiently strong to be tracked to the implantation site without breaking.

Appellant respectfully submits that the proposed modification of Laske et al. would not have been obvious to a person with ordinary skill in the art. Appellant reiterates the assertion that Laske et al. teaches away from making the selective modification, as suggested in the Answer. Appellant respectfully submits that the proposed modification of Laske et al. would not have been obvious to a person with ordinary skill in the art because Laske et al. teaches away from the proposed modification. The purpose of element 152 of Laske et al. is to create a weakened portion. (*See* Laske et al., col. 7, lines 15-31.) To use hindsight reconstruction and say element 152 could be made to extend only partially around the perimeter to strengthen the lead is opposite of what the reference describes, and would frustrate the purpose of element 152, that is, to allow the lead to separate. Element 152 of Laske et al. is designed to allow for a weakened portion of the lead, which teaches away from trying to use the same element to make the lead stronger. Therefore, Applicant respectfully submits that the proposed combination would not have been obvious to a person with ordinary skill in the art.

In brief, Appellant submits that the Answer has failed to meet the burden of proof for a showing of obviousness by the proposed modification.

SUMMARY

For the reasons argued above and in the Appeal Brief, Appellant respectfully submits that claims 1-20 were not properly rejected under either § 102(b) or § 103(a). It is respectfully submitted that the claims are patentable over the cited art. Therefore, Appellant respectfully requests reversal of all bases of rejection and allowance of all claims.

Respectfully submitted,

JAMIE L. RUGNETTA ET AL.

By her Representatives,

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Date July 9, 2007 By

Michael P. Horvath
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 9 day of July, 2007.

Name

Signature